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#39

Francis A. Cooch
Office of Patent Counsel
Johns Hopkins University Applied Physics Laboratory
11100 Johns Hopkins Road
Laurel MD 20723-6099

In re The Johns Hopkins University :
U.S. Patent No. 4,373,527 :
_____ :

NOTICE OF FINAL DETERMINATION OF INELIGIBILITY

On January 28, 2000, The Johns Hopkins University filed application for interim extension under 35 U.S.C. § 156(d)(5) of the patent term of U.S. Patent No. 4,373,527. Interim extension is sought based upon premarket review under § 515 of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a product known as Minimed 2007. A determination has been made that U.S. Patent No. 4,373,527 is NOT eligible for interim patent term extension under 35 U.S.C. § 156 at this time.

The application is dismissed.

A single request for reconsideration of this final determination of ineligibility may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are applicable to this time period. See 37 CFR 1.750.

On page 5 of the application for interim extension, applicant explains that an application for product approval (Application No. P910047) was submitted on August 6, 1991, but was shortly thereafter withdrawn and has not been resubmitted.

35 U.S.C. § 156(d)(5)(A) states, in part (emphasis added):

> If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in...(3)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may be extended beyond the expiration of the patent term in effect, the owner or its agent may submit an application to the Commissioner for an interim extension during the period beginning 6 months, end ending 15 days before such term is due to expire.

35 U.S.C. § 156(g)(3)(B)(ii) states:

> the period beginning on the date an application is initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the

date the protocol was declared completed under section 515(f)(6).

An application for interim extension under 35 U.S.C. § 156(d)(5) may only be filed after the approval phase of a regulatory review period of a product has begun. The approval phase of a product is defined in paragraphs (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), and (5)(B)(ii) of 35 U.S.C. § 156(g). See also 37 CFR 1.790(a). The approval phase of a medical device is defined in 35 U.S.C. § 156(g)(3)(B)(ii) and begins with the date an application with respect to the device (an application for premarket approval (PMA)) or a product development protocol is initially submitted under section 515 of the Federal Food, Drug and Cosmetic Act. Application No. P910047 (the withdrawn application) is not an application which the review thereof can be reasonably expected to extend beyond the original expiration date of the patent. Since applicant has not submitted a PMA which is undergoing review by the Food and Drug Administration, the application for patent term extension is premature and must be dismissed.

DECISION

Under the circumstances of this application, for the reasons set forth above, it is held that U.S. Patent No. 4,373,527 is not eligible for interim extension of the patent term under 35 U.S.C. § 156(d)(5) at this time. Accordingly, the application for extension of the patent term is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Senior Legal Advisor, Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDEV
Food and Drug Administration
1451 Rockville Pike HFD-7
Rockville, MD 20852

RE: Minimed 2007
FDA Docket No.: